REMARKS

This paper is responsive to the Office Action dated April 26, 2005, which is the first action on the merits of the application.

Claims 1-25 are pending in this application, and stand variously rejected.

Further consideration and allowance of the application is respectfully requested.

Amendment to the specification:

The priority application information has been updated, as requested in the Office Action.

New matter rejection:

Claims 1-25 stand rejected for containing subject matter not described in the specification. The Office Action states that there is no basis in the specification as filed for a method of producing a compound.

Applicant respectfully disagrees for three reasons. First, all of the claims as previously presented were original claims in the application as filed. Disclosure in an originally filed claim satisfies the written description requirement. *In re Gardner,* 178 USPQ 149 (CCPA 1973); *Union Oil Co. of California v. Atlantic Richfield Co.,* 54 USPQ2d 1227 (Fed. Cir. 2000).

Second, lines 27-29 of the substitute specification describes the use of purified telomerase to identify and test regulators, inhibitors or activators of telomerase activity in vitro. Page 2, lines 30-32 describe how biochemical analysis of the enzyme's mechanism can provide insight for development of mechanism-based regulators. Page 20, lines 28-32 describes telomerase inhibitors and methods of assaying for them, incorporating into the specification by reference USSN 08/288,501. Thus, the specification explicitly or inherently includes a producing step in conjunction with the assessment of regulators, inhibitors or activators of telomerase activity.

The disclosure as originally filed need not provide in haec verba support for the claimed subject matter at issue. . . . The requirement is met if 'the disclosure of the application relied upon reasonably conveys to the artisan that the inventor has possession at that time of the later claimed subject matter.' *Lampi Corp. v. American Power Products, Inc.*, 56 USPQ2d 1445 (Fed. Cir. 2000).

Third, the Office has already confirmed that the claims have adequate support in the priority applications. In making the double patenting rejection with respect to U.S. Patent Nos. 6,517,834 and 6,787,133 on page 5, the Office Action states:

> The subject matter claimed in the instant application is *fully disclosed* in the patent and is covered by the patent since the patents and the application are claiming common subject matter, as follows: A method for assessing a regulator of telomerase, which uses the obvious variation of method steps of measuring the telomerase activity in the presence of a regulator, where the regulator is a telomerase inhibitor or activator, *and having identified the regulator producing the same.* [italics added]

Other than the claims, the present application has the same specification as the previous patents, and therefore provides a full disclosure of the claimed invention, in accordance with the requirements.

For all of these reasons, the invention claimed here is fully disclosed in the present application as filed and in the priority documents.

Withdrawal of this rejection is respectfully requested.

Rejections under 35 USC § 112 ¶ 1:

Claims 1-25 stand rejected under the written description requirement of § 112 ¶ 1.

First, the Office Action is concerned that there is no reference in the claims of the size or structure of the mammalian telomerase used other than the range of molecular weight.

Actually, the claims also require that the telomerase enzyme have telomerase activity, and some of the dependent claims provide further structural or functional features. Even so, the skilled reader will recognize that the practice of the invention does not need further knowledge of the structural aspects of the purified telomerase in order to practice the claimed method. Other uses of telomerase may benefit from further characterization of the protein, but the role of telomerase in the method claimed here is its ability to serve as a key ingredient in a *functional assay*.

As explained in the specification and in previous patents in this series, the makers of this invention have described for the first time a procedure whereby telomerase protein with telomerase enzyme activity can be purified from mammalian cells that express it. Even in cells that endogenously express telomerase at a high level, there are only a few hundred copies per cell. Previous efforts to make purified telomerase failed *inter alia* because of the paucity of the enzyme inside the cell, and the tendency of it to co-purify with other transcriptase proteins.

The priority application provides for the first time purified preparations that are sufficiently enriched to enable the screening of telomerase inhibitors and activators. Since publication of the earlier applications in this series, the use of purified telomerase for screening has been utilized extensively by other pharmaceutical companies: see, for example, WO 01/07020.

Purified telomerase protein for use in the screening method claimed here can be adequately identified by telomerase activity assay such as those described in the specification (pages 17-23). Since there is no other mammalian enzyme that has telomere elongation activity in such assays, there is no need to recite additional structural features for the reader to distinguish the telomerase enzyme used in the claimed method from other proteins.

The second concern raised in the Office Action under the written description requirement of § 112 ¶ 1 is that there is no regulator that has been identified in the specification.

Of course, there is no need for the specification to provide working examples of the claimed invention. Nevertheless, inhibitors of telomerase are identified in Table 1, page 17; and page 39, lines 18-19. Applicant filed the priority application in this series before undertaking a more extensive screening survey, since the specification fully enables the user to carry on his or her own screening assays in accordance with the invention.

The decisive issue here is that the claims in this application cover the use of purified telomerase enzyme in a screening method. There is no claim to a telomerase regulator identified by the claimed method as a composition of matter. For this reason, the prohibition against reach-through claims made in *University of Rochester v. G. D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) does not apply.

Withdrawal of these rejections is respectfully requested.

Rejection under 35 USC § 112 ¶ 2:

Claims 20 and 21 stand rejected under § 112 ¶ 2 as being indefinite for the use of the term "telomerase core enzyme".

Applicant maintains that the term is fully described in the specification. Nevertheless, the claim has now been amended to refer just to "telomerase enzyme". Withdrawal of this rejection is requested.

Double Patenting

Claims 1-25 stand rejected under the judicially created doctrine of obviousness type double patenting with respect to claims 18-20 of U.S. Patent 6,517,834, or claims 1-25 of U.S. Patent 6,787,133. Both of these prior patents are wholly owned by Geron Corporation, the same entity that owns the present application. The subject matter covered by the claims in this application is different but allegedly covers common subject matter as the cited patents.

Applicant hereby agrees to file Terminal Disclaimers with respect to both these patents, or otherwise address this issue, upon determination that the application is otherwise allowable.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests a further interview by telephone.

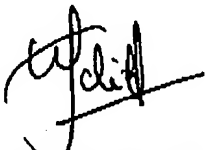
Fees Due

No fee is required with respect to the amendments to the claims, since the claim count has not been changed.

Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



J. Michael Schiff
Registration No. 40,253

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Telephone: (650) 473-7715
Fax: (650) 473-8654

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